

REMARKS

This is in response to the Official Action of March 23, 2004 for the above-identified application. Claims 3 and 4 are pending in this application. Claim 3 is allowed. Claim 4 is amended to advance prosecution, without prejudice to the subject matter cancelled by amendment. Applicant reserves the right to continue prosecution of the cancelled subject matter in continuation or divisional applications.

Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, for lacking enablement for the scope of claim.

For reasons set forth below, the pending rejection should be withdrawn and the application should be allowed to issue.

Claim Rejection under 35 U.S.C. § 112

The Examiner has rejected Claim 4 under 35 U.S.C. § 112, first paragraph, contending that the specification, while being enabling for at least some treatment effect for certain cancer types such as melanoma and certain other specific human cancers, does not reasonably provide enablement for cancer types for which there is no significant basis for treatment effect due to mda-7 administration. In particular, the cancer types that the Examiner has characterized as “generic” and not enabled include lung cancer, connective tissue cancer, nervous system cancer, lymphoma and leukemia. The Examiner further alleges that undue experimentation would be required to support the enablement of these generic cancer types.

Applicant respectfully submits that Claim 4 is enabled because:

(1) As regards lung cancer, the disclosure in the specification is supported by experimental data, in that efficacy has been documented for five lung cancer cell lines (Mhashilkar et al., 2001, Mol, Med, 7: 271-281, Exhibit 1) and a mesothelioma (Cao et al., 2002, Mol Med. 8:869-876, Exhibit 2).

(2) As regards connective tissue cancer, the disclosure in the specification is supported by experimental data, in that efficacy has been documented for cell lines from osteosarcoma and fibrosarcoma type connective tissue cancers (Sauane et al., 2003, J. Cell. Physiol. 196:334-345, Exhibit 3) and vascular smooth muscle cells (Chen et al., Mol Ther. 2003, 8:220-229, Exhibit 4).

(3) As regards generic nervous system cancer, generic lymphoma and generic leukemia, Applicant has amended instant Claim 4 to exclude said cancer types, to advance prosecution. Applicant reserves the right to continue prosecution of the non-elected claims and subject matter in continuation or divisional applications.

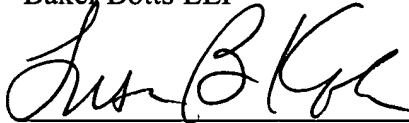
A PTO form 1449 listing the references cited as Exhibit 1-4 is enclosed herewith.

The Applicant therefore respectfully submits that the instant disclosure in Claim 4 supplies significant evidence and reasoning to support effectiveness of mda-7 administration for treating of claimed cancer types as instantly disclosed based on additional support cited in the response above. As a result, the Applicant requests the withdrawal of the rejection of Claim 4 made under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Based on the foregoing remarks, Applicant submits that the present application is in condition for allowance. A Notice of Allowance is respectfully requested. Should any additional fees be required in connection with this response, the Commissioner is hereby authorized to charge Deposit Account Number 02-4377. A duplicate of this page is enclosed.

Respectfully submitted,
Baker Botts LLP

A handwritten signature in black ink, appearing to read "Lisa B. Kole", written over a horizontal line.

Lisa B. Kole
Patent Office Reg. No. 35,225

30 Rockefeller Plaza
New York, NY 10112

Attorney for Applicants
(212) 408-2500